FDA Regulation of Cigarettes Makes No Sense

Despite its deceptive and disarming simplicity, the Synar proposal (H.R. 2147) for the FDA to regulate cigarettes makes no sense. It would divert the already inadequate resources of FDA away from the safety of the nation's food, drugs and medical devices to the regulation of a product that its very critics claim can never be made "safe" or "safer." So why do it?

What Benefits Will Be Achieved by FDA Regulation of Cigarettes?

- No further regulation of cigarettes is needed.

  -- Cigarettes are already extensively regulated at all levels of government. And, the main focus of proposed FDA regulation -- tobacco ingredients and constituents -- is already within the federal government's responsibility. For example, the major cigarette companies have been providing HHS with an annual ingredients list since 1986 and HHS already is authorized to review the health effects of such ingredients. Also, information about constituent levels in cigarettes already is disclosed to the FTC and the public by voluntary agreement. There is no reason to supplant the existing reporting and review mechanisms or to conclude that they are inadequate.

- Product safety is not the real purpose of H.R. 2147.

  -- Ensuring product safety is one of the FDA's core functions. Yet, the goal of anti-smoking advocates is not to ensure the "safety" of tobacco products, but to discourage people from buying them altogether.

  -- Specific concern over cigarette ingredients similarly is not the real impetus. The federal government has known the ingredients in cigarettes for almost eight years and, to date, it has not indicated that its review has created any basis for concern. Indeed, former HHS Secretary Sullivan testified before a congressional committee that ingredients are a "peripheral" concern and that additional regulation is not necessary.

  [Moreover, all the ingredients used by the major cigarette manufacturers have been approved by one or more of the following entities for use in foods or cigarettes: the FDA, the Flavor Extract Manufacturers Association, the United Kingdom Independent Committee on Smoking and Health, or the responsible regulatory agencies of Canada, Belgium, Switzerland, Germany, France and the Council of Europe.]

2023001756

Source: https://www.industrydocuments.ucsf.edu/docs/rhxj0000

- Greater public awareness also is not a realistic goal of FDA regulation. Cigarette packages already bear sizeable health warnings, and surveys show that more Americans know about the claimed risks of smoking than know the name of our first President. Are smokers any more likely to quit because of some incomprehensible list of chemical names of ingredients?

- Ironically, through its authority to approve ingredients, the FDA would be officially endorsing certain brands of cigarettes while rejecting others.

What Are the Costs of FDA Regulation of Cigarettes?

- The FDA's insufficient human and budgetary resources already have hampered its ability to adequately address its extensive and growing list of congressionally mandated responsibilities. (Since 1980, Congress has passed over 50 laws that affect the Agency's responsibilities.)

- The financial costs of an entirely *new* regulatory regime, testing laboratories and administrative bureaucracy will be enormous and, despite the bill's imposition of user fees, taxpayers and consumers inevitably will bear some of the burden, including the price of a less effective FDA.

- If the FDA moves to the center of the smoking controversy, it will be besieged by anti-smoking groups, smokers, and tobacco companies, each petitioning for rules and regulations and tying up the agency's policymakers, scientists and lawyers in regulatory knots.

If the Costs of Regulating Cigarettes So Clearly Outweigh the Benefits, Why Is FDA Regulation Being Proposed?

- Proposed FDA regulation simply is intended to obstruct the sale and marketing of cigarettes by imposing punitive and disparate treatment of cigarette products. Its purpose is to subject cigarettes to such pervasive and unreasonable regulation that they become prohibitively expensive, unpalatable and/or inaccessible.

  -- For example, under H.R. 2147, an instant ban could be implemented on all products currently on the market pending the Agency's review of tobacco ingredients, because the FDA is required to find tobacco ingredients to be "safe" before they can be used. The bill does not recognize the concept applicable to foods that certain ingredients are generally recognized as safe ("GRAS") and, thus, do not need preapproval.

2023001757

Source: https://www.industrydocuments.ucsf.edu/docs/rhxj0000

-- Even short of an outright suspension or ban on marketing pending review, anti-smoking advocates could use the FDA process, which is subject to manipulation by any interested party, to effectively ban certain brands by pressing the FDA to prohibit or restrict key flavor additives.

-- The bill effectively would prohibit truthful descriptors like low-tar, low-nicotine and nicotine-free, effectively driving these products off the market.

-- Testing of tobacco products for every minute constituent, to meet the bill's labeling requirements, would take years to accomplish and could keep cigarettes off the market in the meantime.

-- "Nontraditional" tobacco products would be regulated as drugs, meaning that they couldn't be marketed at all because drugs must have demonstrated therapeutic benefits before they can be sold. This affects not only innovative new products, but conceivably even products on the market today, since the bill leaves it to the FDA to define the term "cigarettes."

-- Cigarettes could become essentially unmarketable. The FDA's sweeping power to dictate the content, form and means of required tobacco product warnings and require any other type of public disclosure, combined with the bill's onerous and unparalleled ingredient and constituent disclosure requirements, could lead to the obliteration of the cigarette pack face and reduce ads to a statement that effectively says, *"Don't Buy This Product."*

- Anti-smoking activists know that Congress will never again vote for "prohibition." That's why they're seeking FDA regulation instead -- to achieve *de facto* prohibition over time.

2023001758

Source: https://www.industrydocuments.ucsf.edu/docs/rhxj0000